

WEDNESDAY, SEPTEMBER 22, 2010 1:00PM – 3:30PM

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procedure and the use of DESs. Long-term follow up with larger population will be necessary to get the clear conclusion.

TCT-195

Quality Of Life After Percutaneous Coronary Interventions: COURAGE Results Apply to the Real World?

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BACKGROUND: The results of the COURAGE study have been questioned, because of the inclusion of a highly selected population. We compared the quality of life (QOL) of patients seen in daily clinical practice with those of the COURAGE study.

METHODS: Prospective observational study of patients with stable angina undergoing PCI at a referral center. The clinical and angiographic characteristics were evaluated, and the Seattle Angina Questionnaire (SAQ) was applied before the procedure and after 6 and 12 months. The data were compared with those reported in the COURAGE study (NEJM 2008;359:677). The t test, chi-square test and multivariate analysis were used.

RESULTS: The study included 110 patients from September 2006 to May 2007. When compared to the COURAGE study, our sample had a higher percentage of women (38% vs 15%), hypertension (82% vs 66%) and prior PCI (29% vs 15%) ($p < 0.001$). Our patients had significantly lower rates of baseline QoL than those in the COURAGE (30 ± 22 vs 51 ± 25, $p < 0.001$), with higher improvement in 12 months (83 ± 22 vs 76 ± 21, $p = 0.002$). The mean change in SAQ was 53 ± 20 in our study versus 25 ± 12 in the COURAGE ($p < 0.01$). By multivariate analysis, regular or poor QOL before the procedure was the main predictor of improvement of QOL at 6 months in both studies.

CONCLUSIONS: Our patients presented a profile of greater severity and worse QOL before PCI than those of the COURAGE trial, with more marked improvement in the follow-up. As the baseline QOL is the main predictor of improvement of this index, these results suggest that the COURAGE results may underestimate the benefit of PCI in daily clinical practice.

Carotid Disease

(Abstract Nos 196-206)

TCT-196

Carotid Sinus Reactions During Carotid Artery Stenting

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Background: Hypotension and bradycardia frequently occur during carotid artery stenting (CAS) that involves the carotid bulb. To determine the influence of carotid sinus reactions (CSR) on outcomes during CAS we retrospectively reviewed in a prospectively collected database of 861 CAS procedures at our institution.

Methods: Of 861 consecutive CAS procedures, 683 (79.3%) had stenting involving the carotid bulb and were included in this study. All pts were enrolled in various Institutional Review Board Clinical trials. Of those 683 study pts, 406 (59.4%) had CSR, which was categorized by severity: Group 1) minor hypotension and/or bradycardia ($n=144$); Group 2) prolonged hypotension and/or bradycardia requiring the use of vasopressors ($n=198$); Group 3) prolonged hypotension and/or bradycardia with transient loss of contralateral hand grip ($n=19$); Group 4) asystole (>6 sec) with hypotension requiring vasopressors ($n=38$); and Group 5) CVA with hypotension and/or bradycardia ($n=7$). CSR pts were then compared to a control group of the 277 pts who had CAS in the carotid bulb and did not have CSR. Continuous variables were expressed as means ± SD, and categorical variables as percentages. Univariate analyses were assessed by two sample Student's t-tests for continuous variables and by Pearson's chi-square analysis for categorical variables. Multivariate stepwise logistic regression analysis was performed to identify independent predictors of CSR. A p-value of <0.05 was considered statistically significant.

Results: Of the 683 patients studied, 344 underwent right CAS and 339 underwent left CAS. There were no differences between the groups with respect to age, symptoms, co-morbidities, or lesion morphology and CSR. Most significant was the correlation between CSR related asystole and right sided CAS vs. left (9.8% vs. 1.1%, $p < 0.001$). In addition, contralateral carotid occlusion or bilateral ($\geq 70\%$) carotid artery stenosis ($p < 0.05$), and history of smoking ($p = 0.01$) and female gender ($p < 0.05$) were independent risk factors for asystole and CVA.

Conclusion: CSR occurred in nearly 60% of the study population. The rate of neurological complications, however, did not significantly increase. It appears, at least in this study that the right carotid baroreceptor is far more sensitive than the left carotid and is an independent risk factor for asystole during CAS especially in the presence of a compromised contralateral carotid artery, history of smoking and female gender.

TCT-197

IIb/IIIa Inhibition In Carotid Artery Stenting Eliminates the Effect Of Age On Stroke Risk

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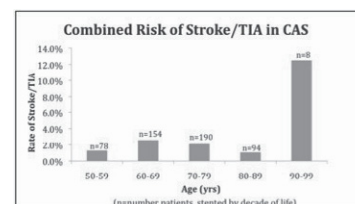
Background: Stroke risk with carotid artery stenting (CAS) increases with age (CREST). IIb/IIIa inhibition with CAS may negate this risk. We report the largest single center experience with IIb/IIIa use in CAS and show no increased risk with age up to 89 years.

Methods: We reviewed 573 consecutive patients who underwent ad-hoc CAS at Baptist Medical Center - Princeton, Birmingham, AL between August, 1999 - August, 2009. Of these, 538 patients were administered a IIb/IIIa inhibitor (eptifibatide, $n=536$, abciximab, $n=2$) as adjunctive antiplatelet therapy and this group forms the basis of this report.

Results: The majority of patients (69.5%) were asymptomatic with positive atherosclerotic risk factors of hypertension, coronary artery disease, hyperlipidemia and history of smoking. The overall

procedural success rate was 99.3% and an embolic protection device was used in 95.2% of cases. Mean carotid stenosis was 85.6% pre-procedure and 4.8% post-procedure. A total of six strokes and five TIAs were recorded and their distribution by age is shown in Figure 1.

Figure 1. In-hospital Incidence of Combined Stroke and TIA by Age
Patients between the ages of 70-89 had lower rates of combined stroke/TIA than those aged 60-69 years. There was no incidence of stroke ($n=1$ TIA) in the 90-99 age group.



Conclusions: Periprocedural use of IIb/IIIa inhibition as adjunctive antiplatelet therapy in CAS may eliminate the age-related increased risk of stroke. Whether CAS with adjunctive IIb/IIIa inhibition decreases the stroke/TIA risk compared to carotid endarterectomy (CEA) in elderly patients should be studied in a randomized trial.

TCT-198

Carotid Artery Stenting Versus Medical Therapy: A Meta-analytic Approach to Determine the Best Treatment for High-risk Patients

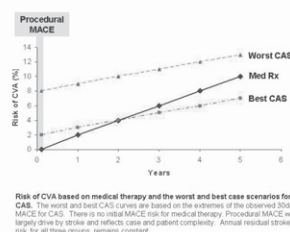
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Background: Carotid artery stenting (CAS) is a viable strategy for patients who are high risk for carotid endarterectomy (CEA). The major limitation of CAS is post-procedural stroke. The morbidity of revascularization must be weighed against a conservative medical approach, particularly for patients with limited long-term survival.

Goal: A meta-analytic approach was used to determine the utility of high risk CAS versus medical therapy only for stroke prevention.

Methods: Among 12 high risk CAS registries, the 30-day risk of death, stroke and MI (procedural MACE), ranged from 2-8%. Regardless of the procedural outcome and the patient population, results from SAPHIRE, CREST, and our institutional database reveal that the subsequent annual risk of ipsilateral stroke is 1.5%/year. The procedural MACE rates were combined with the annual stroke rates to construct curves that represent the stroke risk for the best and worst case scenarios of CAS. These curves were plotted with the results from the 2 major trials of medical therapy, ACAS and ACST, which demonstrated stroke rates of 2% year.

Results: For patients achieving best CAS, stroke outcomes of CAS and medical therapy reach equality after 2 years. At 3 years, CAS is better, but with a NNT of ~100. For worst CAS, the benefits of revascularization will never be realized. Revascularization benefit in high risk patients may be limited by 30% 3-year mortality, which is unrelated to CAS. Thus, patients may not live long enough to offset the early risks of CAS.



Conclusions: The long term benefit of CAS is driven by procedural MACE. The benefit of CAS is only observed when low procedural complication rates can be achieved. Randomized clinical trials are needed to define the utility of revascularization for these patients.

TCT-199

Carotid Angioplasty and Stenting in Octogenarians is as Safe as Surgery

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Purpose: Recent studies, registries (EXACT, CAPTURE) randomized studies (CREST) have shown that carotid angioplasty stenting (CAS) is at higher risk than surgery (CEA) in elderly patients. The aim of this study was to evaluate if CAS performed in octogenarians is as safe as surgery with better indications, choice of the devices, experienced operators.

Methods: 1004 patients (male 733) mean age 70.9 ± 9.4 years underwent 1064 CAS for de novo lesions ($n=982$) restenoses ($n=56$) post radiation ($n=14$) inflammatory arthritis ($n=10$) post trauma aneurysms ($n=2$). Indications for treatment: symptomatic carotid stenosis $> 70\%$ (63%) or asymptomatic stenosis $> 80\%$. Patients were separated into 2 age groups: > 80 y (144 patients, 147 CAS) and < 80 y (860 patients, 917 CAS). 188 CAS performed without protection (N.P-) 6 in patients > 80 y, 876 with protection (NP+) (occlusion balloon: 334, filters: 537, reversal flow: 6) 141 in patients > 80 y. Data analysis included neurological complications, death and myocardial infarction (MI) rate at 30 days,